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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,464	03/09/1999	KOHSUKE KINO	06501/024001	2927

7590 12/04/2001

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n N .	Applicant(s)	
	09/202,464	KINO ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/9/99; 7/6/99; 11/27/00; 9/24/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,11,13,14,17 and 20-28* is/are pending in the application.

4a) Of the above claim(s) *2, 7, 11, 13-14, 17 and 20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-3, 5, 7, 11, 13, 14, 17 and 20-28 are pending.

2. Applicant's election with traverse of Group I, Claims 1, 3 and 5, drawn to Cha o1 peptides, filed 9/24/01, is acknowledged. The traversal is on the grounds that (1) this application was filed under § 371 and entitled to "unity of invention" and not to the US rules of restriction practice; (2) the lack of a special technical feature that defines the contribution of the instant invention over Ikagawa et al cannot rendered obvious because Ikagawa et al discloses peptides and analog thereof from Cry 1 j, which is a polypeptide of Japanese cedar pollen whereas the peptides of instant application is derived from Cha o1 and Cha o 2 which are polypeptides of Japanese cypress pollen. However, WO 94/01560 publication (Jan 1994, PTO 1449) teaches a peptide such as CJI-26, comprising at least one T-cell epitope of pollen allergen consisting of an amino acid sequence which is identical to the claimed peptide #1-26 (SEQ ID NO: 28) of instant application (See Fig 13 of WO94/01560, in particular). Since Applicants' inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and therefore lack unity of invention under § 371. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 2, 7, 11, 13-14, 17 and 20-28 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Applicant should amend the first line of the specification to reflect the relationship between the instant application and PCT/JP97/02031, filed 6/12/1997 stated on the oath.

5. The proposed amendments to the drawings filed 7/6/99, is granted. Applicant is reminded that the Patent and Trademark Office no longer makes drawing changes and that it is applicant's responsibility to ensure that the drawings are corrected. Alternatively, Applicants may amend the Brief Description of the Drawings to incorporate the SEQ ID NOS.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) a peptide consisting of at least one or two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 and consisting of amino acid sequence selected from the group consisting of peptide of SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 shown in Fig 4, (2) a composition comprising said peptide and an acceptable diluent or carrier for in vitro diagnosis of pollinosis and peptide-based immunotherapy, does not reasonably provide enablement for (1) *any* peptide "comprising" of at least one or two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 and consisting of amino acid sequence selected from the group consisting of peptide of SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 shown in Fig 4 and (2) *any* part of said amino acid sequence for in vitro diagnosis or peptide based immunotherapy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only (1) a peptide consisting of at least one or two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 and consisting of amino acid sequence selected from the group consisting of peptide of SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 shown in Fig 4, (2) a composition comprising said peptide and an acceptable diluent or carrier for in vitro diagnosis of pollinosis and peptide-based immunotherapy.

The specification does not teach how to make and use a peptide "comprising" any peptide mentioned above because there is no guidance as to what type and number of amino acids can be added to said peptides of SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 and whether after

addition of amino acids would retain the structure and function similar to said peptides. The transitional phrase "comprising" is open-ended and it expands the peptide to include additional amino acids at either end. By reciting the term "comprising" in the claim, the peptide encompasses indefinite number and type of additional amino acids, in addition to the amino acids which already recited in SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36. Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure/function will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). Given the indefinite number of undisclosed peptide with unspecified length, it is unpredictable as to which peptide "comprising" at least one T-cell epitope of Japanese cypress pollen allergen Cha o 1 will be useful for peptide based immunotherapy.

With regard to "a part of said amino acid sequence" as recited in claim 1, the specification fails to provide any guidance as to what part of any peptide mentioned above can be deleted and still retain both structure and function. Given the insufficient guidance and working examples, predicting what changes can be made to the amino acid sequence mentioned above that after deletion will retain both structure and have similar function is unpredictable. Since the claim encompassed an indefinite number of undisclosed peptide with unspecified length, it follows that "a part of said amino acid sequence" is not enabled. *In re Fisher*, 1666 USPQ 19 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

For these reasons, the specification as filed fails to enable one skill in the art to practice the invention without undue amount of experimentation. As such, further research would be required to practice the claimed invention.

8. Claims 1, 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) *any* peptide "comprising" of at least one or two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 and consisting of amino acid sequence selected from the group consisting of peptide of SEQ ID

NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 shown in Fig 4 and (2) *any* part of said amino acid sequence for in vitro diagnosis or peptide based immunotherapy.

The specification discloses only (1) a peptide consisting of at least one or two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 and consisting of amino acid sequence selected from the group consisting of peptide of SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 shown in Fig 4 and (2) a composition comprising said peptide and an acceptable diluent or carrier for in vitro diagnosis of pollinosis and peptide-based immunotherapy.

With the exception of the peptide **consisting** SEQ ID NOS: 4, 6-10, 12-14, 16-18, 21-29, 32-36 shown in Fig 4 having T cell stimulating activity, there is no description about the structure associated with function of *any* peptide "comprising" of at least one or two T-cell epitopes mentioned above and "a part of said amino acid sequence". The term "comprising" is opened-end. The claims encompass an indefinite number of undisclosed peptides that read on the full-length polypeptide. Since the peptides "comprising" at least one T-cell epitope are not adequately described, it follows that *any* peptides "comprising" at least one or two T-cell epitopes and *any* part said amino acid sequence are not adequately described. Further, the specification fails to describe additional representative species of a part of said amino acid sequence mentioned above.

Given the lack of a written description as encompassed by the claims, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.* Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/01560 (Jan 1994; PTO 1449).

The WO 94/01560 publication teaches a peptide such as CJI-26 (251-270) comprising at least one T-cell epitope of pollen allergen and consisting of an amino acid sequence identical to the claimed peptide #1-26 of SEQ ID NO: 28 or a part (portion) of said amino acid sequence (See Fig 13 of WO 94/01560, claims of WO 94/01560, in particular). Furthermore, the term "comprising" is open-ended. It expands the claimed peptide to read on the reference full-length polypeptide of SEQ ID NO: 2. Claim 3 is included in this rejection because the reference full-length polypeptide comprises at least two T-cell epitopes. The publication further teaches a composition comprising the reference peptide and a pharmaceutically acceptable carrier or diluent for peptide-based immunotherapy (See claim 68 of WO 94/01560 publication, in particular). Thus, the reference teachings anticipate the claimed invention.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
December 3, 2001

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